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# REVISED ENVIRONMENTAL ASSESSMENT

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|---|---|---|
| 1. | **Date** | May 24, 1999 |
| 2. | **Name of Applicant/Petitioner** | Ticona |
| 3. | **Address** | All communications on this matter are to be sent in care of Counsel for Petitioner, Jerome H. Heckman, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001. Telephone: (202) 434-4110. |

## 4. Description of the Proposed Action

The action requested in this Petition is the amendment of an existing Food Additive Regulation to expand the permitted uses of olefin polymers in articles or components of articles that may contact food. Its specific purpose is to amend 21 C.F.R. § 177.1520(a)(3) to provide for use of ethylene-2-norbornene copolymers containing not less than 30 but no more than 70 mole percent of polymer units derived from norbornene. Such copolymers would be limited to use with dry foods containing no free fat or oil (Food Type VIII, identified in § 176.170(c), Table 1).

We note that, while FDA promulgated regulations, effective August 29, 1997, amending its requirements for environmental assessments (EA's), the Agency has not yet made available guidance documents for preparing EA's under the new regulations. Consequently, the EA presented here has been prepared in accordance with the format requirements that previously appeared at 21 C.F.R. § 25.31a. modified as appropriate to focus on the impact of use and disposal of the subject polymers, in keeping with the new regulations. Since the requirements set forth under new Section 25.40 are less extensive than

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EA-2.

the former requirements, we understand that an EA prepared in accordance with the previous formats will be accepted.

The subject ethylene-norbornene copolymers offer several technical properties that make them useful in a variety of food, pharmaceutical, and medical device applications. In particular, the moisture barrier properties of the polymers make them useful in food and pharmaceutical flexible packaging, and in certain rigid packaging applications (*e.g.*, vials and bottles). The polymers also offer good clarity, and a high heat deflection temperature. The latter is of importance in applications involving steam autoclave treatment of the product.

The uses for the polymers at issue in this petition are limited to dry food contact. These foods are generally packaged either in flexible film or paper and paperboard packaging. They are not generally packaged in rigid containers and are not subject to retort sterilization. Thus, for the applications covered in this petition, the copolymers are expected to be used primarily in film form to produce flexible packaging for dry foods use, where the moisture barrier properties of the polymer will be of greatest value. In addition, the polymers may also be used to produce containers (*e.g.*, bins) that are used to hold bulk quantities of dry food and are generally subject to repeated-use.

The Petitioner does not intend to produce finished food packaging materials from the subject ethylene-norbornene copolymers. Rather, the copolymers will be sold to manufacturers engaged in the production of food-contact materials. Food-contact materials produced with the use of the copolymers will be utilized in patterns corresponding to the national population density and will be widely distributed across the country. Therefore, it is

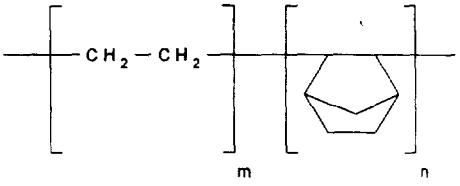
anticipated that disposal will occur nationwide, with about 76% of the materials being deposited in land disposal sites, and about 24% combusted.[1]

The types of environments present at and adjacent to these disposal locations are the same as for the disposal of any other food-contact material in current use. Consequently, there are no special circumstances regarding the environment surrounding either the use or disposal of food-contact materials prepared from ethylene-norbornene copolymers.

## 5. Identification of Substance that Is the Subject of the Proposed Action

The additives that are the subject of this Petition are copolymers of ethylene and 2-norbornene prepared with not less than 30 but no more than 70 mole percent of polymer units derived from 2-norbornene. As dealt with by the petitioner, the copolymers are marketed under the trade name Topas® and referred to as "Topas® COC [cyclic olefin copolymers]."

The Chemical Abstracts Service (CAS) Registry Number for Topas® COC is 26007-43-2; the CAS name is Bicyclo[2.2.1]hept-2-ene, polymer with ethene. The molecular formula is $(C_7H_{10} \cdot C_2H_4)_x$. The structural formulae for the polymer repeating units are as follows:

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[1] *Characterization of Municipal Solid Waste in the United States: 1997 Update*, EPA 530-R-98-007, U.S. Environmental Protection Agency (5305W), Washington DC, 20460, May 1998.

The molecular structure of the polymer consists of varied sequences of the units shown above randomly incorporated along the polymer chain.

**6. Introduction of Substances into the Environment**

Under 21 C.F.R. § 25.40(a), an environmental assessment ordinarily should focus on relevant environmental issues relating to the use and disposal from use, rather than the production, of FDA-regulated articles. Moreover, information available to the Petitioner does not suggest that there are any extraordinary circumstances in this case indicative of any adverse environmental impact as a result of the manufacture of Topas® COC copolymers. Consequently, information on the manufacturing site and compliance with relevant emissions requirements is not provided here.

No environmental release is expected upon the use of the subject copolymers to fabricate packaging materials for dry foods. In these applications, the polymers are expected largely to be used in film form and will be entirely incorporated into the finished food package. Any waste materials generated in this process, *e.g.*, plant scraps, are expected to be disposed of as part of the packaging manufacturer's overall nonhazardous solid waste in accordance with established procedures.

Disposal by the ultimate consumer of food-contact materials produced by the subject copolymers will be by conventional rubbish disposal and, hence, primarily by sanitary landfill or incineration. The subject olefin copolymers consist of carbon and hydrogen. Thus, no toxic combustion products are expected as a result of the proper incineration of the copolymers.

Only extremely small amounts, if any, of Topas® COC copolymer constituents are expected to enter the environment as a result of the landfill disposal of food-contact articles, in light of the Environmental Protection Agency's (EPA) regulations governing municipal solid waste landfills. EPA's regulations require new municipal solid-waste landfill units and lateral expansions of existing units to have composite liners and leachate collection systems to prevent leachate from entering ground and surface water, and to have ground-water monitoring systems. 40 C.F.R. Part 258. Although owners and operators of existing active municipal solid waste landfills that were constructed before October 9, 1993 are not required to retrofit liners and leachate collections systems, they are required to monitor groundwater and to take corrective action as appropriate. The lack of any leaching is especially true considering that the subject substances are high molecular weight polymers that contain only minute levels of extractable material even under conditions that greatly exaggerate environmental exposure conditions.[2/]

## 7. Fate of Emitted Substances in the Environment

### (a) Air

No significant effect on the concentrations of and exposures to any substances in the atmosphere are anticipated due to the proposed use of Topas® COC copolymers. The

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[2/] This expectation is confirmed by the results of extraction studies described in the Appendix to this Environmental Assessment. As shown there, when 157-mil thick bars of the polymer were exposed to water, 3% acetic acid, and 15% ethanol at 100°C for two hours, less than 3 ppb of norbornene monomer was found in the extracts. Moreover, due to the very limited food-contact use requested in this Petition (use with dry foods only), the quantity of ethylene-norbornene copolymer in solid waste deposited in landfills will be extremely small.

polymers are of high molecular weight and do not volatilize. Thus, no significant quantities of any substances will be released upon the use and disposal of food-contact articles manufactured with these copolymers.

The products of complete combustion of the polymer would be carbon dioxide and water; the concentrations of these substances in the environment will not be significantly altered by the proper incineration of the polymers in the amounts utilized for food packaging applications.

**(b) Water**

No significant effects on the concentrations of and exposures to any substances in fresh water, estuarine, or marine ecosystems are anticipated due to the proposed use of the subject copolymers. No significant quantities of any substance will be added to these water systems upon the proper incineration of the polymers, nor upon its disposal in landfills due to the extremely low levels of aqueous migration of polymer components.

**(c) Land**

Considering the factors discussed above, no significant effects on the concentrations of and exposures to any substances in terrestrial ecosystems are anticipated as a result of the proposed use of the subject ethylene-norbornene copolymers. In particular, the extremely low levels of migration of monomer, even at 100°C, demonstrated by the extraction studies, indicate that virtually no leaching of these substances may be expected to occur under normal environmental conditions when finished food-contact materials are disposed of. Furthermore, the very low production of Topas® COC copolymers for use in food-contact applications precludes any substantial release to the environment of their components. Thus, there is no

expectation of any meaningful exposure of terrestrial organisms to these substances as a result of the proposed use of the copolymers.

Considering the foregoing, we respectfully submit that there is no reasonable expectation of a significant impact on the concentration of any substance in the environment due to the proposed use of Topas® COC copolymers in the manufacture of articles intended for use in contact with dry food.

## 8. Environmental Effects of Released Substances

As discussed previously, the only substances that may be expected to be released to the environment upon the use and disposal of food packaging materials fabricated with the use of the subject copolymers consist of extremely small quantities of combustion products and extractables. As discussed in Section E of the Petition, two copolymers, having different percentages of polymer units derived from 2-norbornene, were subjected to acute oral toxicity study in rats demonstrating that the $LD_{50}$ for each test material is greater than 2000 mg/kg bw. In addition, the monomer 2-norbornene is of very low acute toxicity, as demonstrated by an $LD_{50}$ in excess of 11000 mg/kg bw; and the monomer has been shown to be non genotoxic. Based on these considerations, no adverse effect on organisms in the environment is expected as a result of the disposal of articles containing the copolymers. In addition, the use and disposal of the copolymers are not expected to threaten a violation of applicable laws and regulations, e.g., the Environmental Protection Agency's regulations in 40 C.F.R. part 60 that pertain to municipal solid waste combustors and part 258 that pertain to landfills.

**9. Use of Resources and Energy**

As is the case with other food packaging materials, the production, use and disposal of Topas® COC copolymers involves the use of natural resources such as petroleum products, coal, and the like. However, the use of the subject copolymers in the fabrication of food-contact materials is not expected to result in a net increase in the use of energy and resources, since the copolymers are intended to be used in place of similar polymers now on the market for use in food packaging applications. Specifically, as discussed in Item 4 above, the subject copolymers are proposed for use in contact with dry foods only. Due to this limitation, the polymers are expected to be used largely in flexible film packaging to serve as a moisture barrier. Dry foods currently are packaged primarily in similar sorts of flexible film or in paper and paperboard packaging. Polymers currently used in such applications include other olefin polymers that are cleared under 21 C.F.R. § 177.1520 as well as other polymers that are used for their moisture barrier properties, such as polyvinylidene chloride (PVDC).

The replacement of these types of materials by Topas® is not expected to have any adverse impact on the use of energy and resources. Manufacture of the copolymers and conversion to finished food packaging materials will consume energy and resources in amounts comparable to the manufacture and use of other polyolefins. Moreover, the film and paper materials currently in use for dry foods packaging are not recovered for recycling to a significant extent but are disposed of by means of sanitary landfill and incineration. Packaging materials produced from ethylene-norbornene copolymers are expected to be

disposed of according to the same patterns when they are used in place of the current materials. Thus, there will be no impact on current or future recycling programs.

As also noted in Item 4, the subject copolymers may also be used to produce rigid containers for holding food. In this case, based on consideration of current packaging patterns for dry foods, it is expected that the polymers will be limited to use in articles such as bins that are intended for use in holding bulk quantities of dry food. These articles will generally be subject to repeated use and will have a reasonably long service life. Currently used materials that may be replaced by ethylene-norbornene copolymers in these applications are expected to consist of other polymers, including other olefin polymers, acrylics, etc. At the end of their service lives, the articles are expected to be disposed of by standard means (primarily landfill); disposal patterns are expected to be the same as those for the currently used materials. Thus, again there will be no adverse impact on recycling or on solid waste production.

## 10. Mitigation Measures

As shown above, no significant adverse environmental impacts are expected to result from the use and disposal of food-contact materials fabricated from the subject copolymers. This is primarily due to the minute levels of leaching of potential migrants from the finished article; the insignificant impact on environmental concentrations of combustion products of the polymers; and the close similarity of the subject copolymers to the materials they are intended to replace. Thus, the use of the copolymers as proposed is not reasonably expected to result in any new environmental problem requiring mitigation measures of any kind.

## 11. Alternatives to the Proposed Action

No potential adverse environmental effects are identified herein which would necessitate alternative actions to that proposed in this Petition. The alternative of not approving the action proposed herein would simply result in the continued use of the materials which the subject copolymers would otherwise replace; such action would have no environmental impact. In view of the excellent qualities of the Topas® COC polymers for use in food-contact applications, the fact that the copolymer constituents are not expected to enter the environment in more than minute quantities upon the use and disposal of finished food-contact articles, and the absence of any significant environmental impact which would result from their use, the promulgation of a Food Additive Regulation to permit the use of Topas® COC polymers as described herein is environmentally safe in every respect.

## 12. List of Preparers

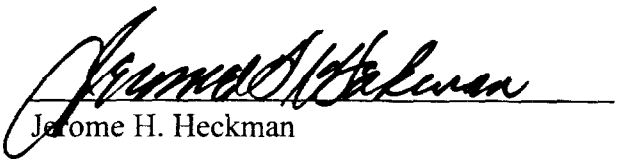
a. Michael T. Flood, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

b. Holly H. Foley, Staff Scientist, Keller and Heckman LLP, 1001 G Street, N.W., Suite 500 West, Washington, D.C. 20001.

**13. Certification**

The undersigned official certifies that the information provided herein is true, accurate, and complete to the best of his knowledge.

Date: May 24, 1999



Jerome H. Heckman

Counsel for Ticona

**14. Appendix**

Attached are data on extraction of norbornene from ethylene-norbornene copolymer test specimens to aqueous media. (These data are referenced in footnote 2, above.)

# Final Report

## Determination of the Potential Migration of Norbornene and Decalin from Cyclic Olefin Copolymers into Food-Simulating Solvents

PREPARED FOR:
Ticona

COVANCE STUDY NUMBER:
6954-101

COVANCE
THE DEVELOPMENT SERVICES COMPANY

Covance Laboratories Inc.
P.O. Box 7545
Madison, Wisconsin 53707-7545
Packages: 3301 Kinsman Boulev
Madison, Wisconsin 53704
Tel: 608/241-4471
Fax: 608/241-7227

Sponsor:

Ticona
Summit, New Jersey

FINAL REPORT

Study Title:

# Determination of the Potential Migration of Norbornene and Decalin from Cyclic Olefin Copolymers into Food-Simulating Solvents

Authors:

Jessie L. Nelson
Melanie M. McCort-Tipton

Study Completion Date:

May 21, 1999

Performing Laboratory:

Covance Laboratories Inc.
3301 Kinsman Boulevard
Madison, Wisconsin 53704

Laboratory Project Identification

Covance 6954-101



000315

## STUDY IDENTIFICATION

Determination of the Potential Migration of Norbornene and Decalin from Cyclic Olefin Copolymers into Food-Simulating Solvents

| | |
|---|---|
| Test Articles | Topas® cyclic olefin polymers (COC) |
| Sponsor | Ticona<br>86 Morris Avenue<br>Summit, New Jersey 07901 |
| Study Monitor | Gerald S. Kirshenbaum<br>Ticona<br>86 Morris Avenue<br>Summit, New Jersey 07901<br>Telephone Number: (908) 522-7662<br>Facsimile Number: (908) 522-3932 |
| Study Director | Melanie M. McCort-Tipton<br>Covance Laboratories Inc.<br>P.O. Box 7545<br>Madison, Wisconsin 53707-7545<br>Telephone Number: (608) 664-3049<br>Facsimile Number: (608) 664-3022 |
| Study Locations | Covance Laboratories Inc.<br>3301 Kinsman Boulevard<br>Madison, Wisconsin 53704<br><br>Covance Laboratories Inc.<br>802 Deming Way<br>Madison, Wisconsin 53717 |
| Study Timetable | |
| Experimental Start Date | December 15, 1998 |
| Experimental Termination Date | February 8, 1999 |

**KEY PERSONNEL**

Agrosciences and Industrial Chemistry

Keith R. Rowley
Associate Director

Melanie M. McCort-Tipton
Staff Scientist/Manager

Paul Severin
Research Assistant

Carol Mesun
Study Coordinator

Jessie Nelson
Study Coordinator

## CONTENTS

## ABSTRACT

This report describes a study that was performed on Topas® cyclic olefin copolymers (COC). The purpose of this study was to determine the potential migration of norbornene and decalin from cyclic olefin copolymers into food-simulating solvents under exaggerated conditions of use.

Analytical methodology was developed to determine norbornene and decalin in 10% and 95% ethanol extracts. The limit of detection (LOD) was 50 ppb (0.5 µg/in.$^2$) for each analyte.

The test articles were extracted, in triplicate, under the following conditions.

| Test Article | Solvent | Temperature/Time |
|---|---|---|
| Topas® 6015 | 10% Ethanol | 121°C for 2 hours, then 40°C for 238 Hours |
| | 95% Ethanol | 121°C for 2 hours, then 40°C for 238 Hours |
| Topas® 8007 | 10% Ethanol | 66°C for 2 hours, then 40°C for 238 Hours |
| | 95% Ethanol | 66°C for 2 hours, then 40°C for 238 Hours |

Samples were removed after 2-, 24-, 96-, and 240-hours of exposure and analyzed for norbornene and decalin. The mean concentrations are presented below and on the following page.

| Sample Identification | Covance Log Number | Norbornene Mean Concentration (µg/in.$^2$) | | | |
|---|---|---|---|---|---|
| | | 2 Hours | 24 Hours | 96 Hours | 240 Hours |
| | | 10% Ethanol | | | |
| Topas 6015 | 8-7972 | <0.501 | <0.501 | <0.501 | <0.501 |
| Topas 8007 | 8-7973 | <0.501 | <0.501 | <0.501 | <0.501 |
| | | 95% Ethanol | | | |
| Topas 6015 | 8-7972 | <0.501 | <0.501 | <0.501 | <0.501 |
| Topas 8007 | 8-7973 | <0.501 | <0.501 | <0.501 | <0.501 |

| Sample Identification | Covance Log Number | Decalin Mean Concentration (µg/in.$^2$) 2 Hours | 24 Hours | 96 Hours | 240 Hours |
|---|---|---|---|---|---|
| | | 10% Ethanol | | | |
| Topas 6015 | 8-7972 | <0.501 | <0.501 | <0.501 | <0.501 |
| Topas 8007 | 8-7973 | <0.501 | <0.501 | <0.501 | <0.501 |
| | | 95% Ethanol | | | |
| Topas 6015 | 8-7972 | <0.501 | <0.501 | <0.501 | <0.501 |
| Topas 8007 | 8-7973 | <0.501 | <0.501 | <0.501 | <0.501 |

Since the analytes were not detected in the extracts, validations were conducted by spiking the 240-hour extracts with norbornene and decalin at the LOD. All fortifications contained detectable levels of the analytes.

## INTRODUCTION

This report describes a study that was performed on Topas® cyclic olefin copolymers (COC). The purpose of this study was to determine the potential migration of norbornene and decalin from cyclic olefin copolymers into food-simulating solvents under exaggerated conditions of use.

The study was divided into three phases.

- Phase I - Method Development
- Phase II - Extraction/Analysis
- Phase III - Validation

## REGULATORY COMPLIANCE

This study was conducted in accordance with the Food and Drug Administration (FDA) "Recommendations for Chemistry Data for Indirect Food Additive Petitions," (June 1995).

## MATERIALS

### Test Articles

The test articles consisted of Topas® cyclic olefin polymers, supplied by the Sponsor. A description of each polymer is presented below. The test articles were at least 20 mils thick.

| Sample Identification | Description | Covance Log Number |
|---|---|---|
| Topas® 8007: | Uses 36% norbornene; HDT of 75°C | 8-7972 |
| Topas® 6015: | HDT of 150°C | 8-7973 |

The test articles were stored under ambient conditions prior to testing. Information on the purity and stability of the test articles at ambient conditions is the responsibility of the Sponsor.

### Test Article Identification

Each test article was identified by a unique Covance identification number. The log numbers are presented in the table above.

Analytical Standard

Analytical standards, of known purity, were obtained commercially for the following.

- Norbornene (norbornylene), 99%, Acros Organic Chemicals
- Decalin (decahydronaphthalene), 98%, Acros Organic Chemicals

Test System

Food Simulating Solvents:

- Ethanol, 95%, Aaper Alcohol Company, Shelbyville, Kentucky
- Ethanol, 10%, prepared from 95% ethanol and water processed through a Milli-Q purification system, Millipore Corporation, Bedford, Massachusetts

Extraction Cells

The two-sided extraction cells consisted of appropriate enclosures capable of withstanding the high pressures generated by heating the extraction solvents past their boiling points. Two sides of the test articles, 120 $in.^2$, were exposed to 700 mL of extraction solvent.

Safety Precautions

Adequate procedures were taken to ensure worker safety and were based on information contained in Material Safety Data Sheets supplied by the Sponsor, as well as those data sheets for the solvents themselves.

## PROCEDURE

Phase I - Method Development

Analytical methodology was developed to determine norbornene and decalin in 10% and 95% ethanol extracts. The limit of detection (LOD) was 50 ppb (0.5 $\mu g/in.^2$). A preliminary validation of the methods and the linearity of the standard response versus concentration was established.

Phase II - Extraction/Analysis

The test articles were extracted, in triplicate, under the conditions outlined on the following page.

| Test Article | Solvent | Temperature/Time |
|---|---|---|
| Topas® 6015 | 10% Ethanol | 121°C for 2 hours, then 40°C for 238 Hours |
| | 95% Ethanol | 121°C for 2 hours, then 40°C for 238 Hours |
| Topas® 8007 | 10% Ethanol | 66°C for 2 hours, then 40°C for 238 Hours |
| | 95% Ethanol | 66°C for 2 hours, then 40°C for 238 Hours |

Samples were removed after 2-, 24-, 96-, and 240-hours of exposure and analyzed for norbornene and decalin using the method developed in Phase I. Each replicate contained sufficient test article to detect the appropriate residue level. The ratio of solvent to surface area was 5.8 mL of solvent per square inch of test article exposed.

Phase III - Validation

Validations were conducted by spiking the 240-hour extracts, in triplicate, with known concentrations of analytes at approximately one half, one, and two times the amount detected. If the analyte was not detected, then the validations were conducted, in triplicate, at the LOD.

## RESULTS

Phase I - Method Development

Methods were developed to determine norbornene and decalin in 10% and 95% ethanol extracts. These methods are presented in Appendix A. Example standard curves demonstrating the linearity of the standards response versus concentration are presented in Appendix B.

Phase II - Extraction/Analysis

The mean concentrations detected in the extracts are presented below. The individual results are presented in Tables 1-4 for norbornene and Tables 5-8 for decalin. Example chromatography is presented in Appendix B.

| Sample Identification | Covance Log Number | Norbornene Mean Concentration (µg/in.$^2$) 2 Hours | 24 Hours | 96 Hours | 240 Hours |
|---|---|---|---|---|---|
| | | 10% Ethanol | | | |
| Topas 6015 | 8-7972 | <0.501 | <0.501 | <0.501 | <0.501 |
| Topas 8007 | 8-7973 | <0.501 | <0.501 | <0.501 | <0.501 |
| | | 95% Ethanol | | | |
| Topas 6015 | 8-7972 | <0.501 | <0.501 | <0.501 | <0.501 |
| Topas 8007 | 8-7973 | <0.501 | <0.501 | <0.501 | <0.501 |

| Sample Identification | Covance Log Number | Decalin Mean Concentration (µg/in.$^2$) 2 Hours | 24 Hours | 96 Hours | 240 Hours |
|---|---|---|---|---|---|
| | | 10% Ethanol | | | |
| Topas 6015 | 8-7972 | <0.501 | <0.501 | <0.501 | <0.501 |
| Topas 8007 | 8-7973 | <0.501 | <0.501 | <0.501 | <0.501 |
| | | 95% Ethanol | | | |
| Topas 6015 | 8-7972 | <0.501 | <0.501 | <0.501 | <0.501 |
| Topas 8007 | 8-7973 | <0.501 | <0.501 | <0.501 | <0.501 |

Phase III - Validation

Since the analytes were not detected in the extracts, validations were conducted by spiking the 240-hour extracts with norbornene and decalin at the LOD. All fortifications contained

detectable levels of the compounds. The individual results are presented in Tables 9-16, while example chromatography is presented in Appendix B.

## DATA AND SPECIMEN RETENTION

When the final report is completed, the items to be transferred to and maintained in the archives of Covance will include, but will not be limited to:

- Protocol
- Test article information
- Test article preparation records
- Test article analysis records
- Study correspondence
- Final report

The following supporting records to be retained at Covance but not archived with the study data will include, but not be limited to:

- Storage location temperature records
- Instrument calibration and maintenance records

Upon acceptance of the final report, any remaining test article will be returned to the Sponsor, or at the Sponsor's request, destroyed.

All raw data, documentation, records, protocols, and final reports generated as a result of this study will be archived by Covance for a period of one year following signing of the final report. At least one year after signing of the final report, all of the aforementioned materials, with the exception of the original final report, protocol, amendments (if necessary), and correspondence, will be sent to a place designated by the Sponsor and a fee will be charged. The Sponsor may elect to have the materials retained in the Covance archives for an additional period of time and Covance will charge a storage fee. If the Sponsor chooses to have Covance dispose of the materials, a disposal fee will be charged.

## STATISTICAL EVALUATION

The mean, standard deviation, and relative standard deviation will be calculated for each group of at least three analyses, where applicable.

Table 1

Analysis of Norbornene in 10% Ethanol Extracts of Topas® 6015

| Sample Identification | Covance Log Number | Replicate | Concentration (µg/mL) | Concentration (µg/in.$^2$)[a] | Mean (µg/in.$^2$) |
|---|---|---|---|---|---|
| | | 2 Hours at 121°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 22 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 94 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 238 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |

NA Not Applicable

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

Table 2

Analysis of Norbornene in 95% Ethanol Extracts of Topas® 6015

| Sample Identification | Covance Log Number | Replicate | Concentration (µg/mL) | Concentration (µg/in.$^2$)[a] | Mean (µg/in.$^2$) |
|---|---|---|---|---|---|
| | | 2 Hours at 121°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 22 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 94 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 238 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |

NA Not Applicable

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

Table 3

Analysis of Norbornene in 10% Ethanol Extracts of Topas® 8007

| Sample Identification | Covance Log Number | Replicate | Concentration (µg/mL) | Concentration (µg/in.$^2$)[a] | Mean (µg/in.$^2$) |
|---|---|---|---|---|---|
| | | 2 Hours at 66°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 22 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 94 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 238 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |

NA Not Applicable

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

Table 4

Analysis of Norbornene in 95% Ethanol Extracts of Topas® 8007

| Sample Identification | Covance Log Number | Replicate | Concentration (µg/mL) | Concentration (µg/in.$^2$)[a] | Mean (µg/in.$^2$) |
|---|---|---|---|---|---|
| | | 2 Hours at 66°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 22 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 94 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 238 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |

NA Not Applicable

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

Table 5

Analysis of Decalin in 10% Ethanol Extracts of Topas® 6015

| Sample Identification | Covance Log Number | Replicate | Concentration (µg/mL) | Concentration (µg/in.$^2$)[a] | Mean (µg/in.$^2$) |
|---|---|---|---|---|---|
| | | 2 Hours at 121°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 22 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 94 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 238 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |

NA Not Applicable

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

Table 6

Analysis of Decalin in 95% Ethanol Extracts of Topas® 6015

| Sample Identification | Covance Log Number | Replicate | Concentration (µg/mL) | Concentration (µg/in.$^2$)[a] | Mean (µg/in.$^2$) |
|---|---|---|---|---|---|
| | | 2 Hours at 121°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 22 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 94 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 121°C, then 238 hours at 40°C | | | |
| Topas 6015 Lot No.970320 | 8-7972 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |

NA Not Applicable

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

Table 7

Analysis of Decalin in 10% Ethanol Extracts of Topas® 8007

| Sample Identification | Covance Log Number | Replicate | Concentration (µg/mL) | Concentration (µg/in.$^2$)[a] | Mean (µg/in.$^2$) |
|---|---|---|---|---|---|
| | | 2 Hours at 66°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 22 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 94 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 238 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |

NA Not Applicable

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

Table 8

Analysis of Decalin in 95% Ethanol Extracts of Topas® 8007

| Sample Identification | Covance Log Number | Replicate | Concentration (µg/mL) | Concentration (µg/in.$^2$)[a] | Mean (µg/in.$^2$) |
|---|---|---|---|---|---|
| | | 2 Hours at 66°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 22 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 94 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |
| | | 2 Hours at 66°C, then 238 hours at 40°C | | | |
| Topas 8007 Lot No. 970205 | 8-7973 | 1 | <0.0858 | <0.501 | <0.501 |
| | | 2 | <0.0858 | <0.501 | |
| | | 3 | <0.0858 | <0.501 | |
| Solvent Blank | NA | 1 | <0.0858 | | |
| | | 2 | <0.0858 | | |

NA Not Applicable

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

Table 9

Validation of Norbornene in 10% Ethanol Extracts of Topas® 6015

| Sample Identification | Covance Log Number | Replicate | Concentration Detected (µg/mL) | | Corrected Concentration Detected (µg/in.$^2$)[b] | Concentration Added (µg/in.$^2$) | Percent Recovery | Mean (%) |
|---|---|---|---|---|---|---|---|---|
| | | | | (µg/in.$^2$)[a] | | | | |
| Topas 6015 | 8-7972 | 1 | 0.0570 c | 0.333 | 0.333 | 0.501 | Detected | Detected |
| Lot No.970320 | | 2 | 0.0291 c | 0.170 | 0.170 | 0.501 | Detected | |
| LOD Spike | | 3 | 0.0858 c | 0.501 | 0.501 | 0.501 | Detected | |
| Topas 6015 | 8-7972 | 1 | <0.0858 | <0.501 | | | | |
| Lot No.970320 | | 2 | <0.0858 | <0.501 | | | | |

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

b Concentration corrected by subtracting the mean level detected in the control, when necessary.

c The value was extrapolated below the standard curve.

Table 10

Validation of Norbornene in 95% Ethanol Extracts of Topas® 6015

| Sample Identification | Covance Log Number | Replicate | Concentration Detected (µg/mL) | Concentration Detected (µg/in.$^2$)[a] | Corrected Concentration Detected (µg/in.$^2$)[b] | Concentration Added (µg/in.$^2$) | Percent Recovery | Mean (%) |
|---|---|---|---|---|---|---|---|---|
| Topas 6015 | 8-7972 | 1 | 0.114 | 0.665 | 0.665 | 0.501 | Detected | Detected |
| Lot No.970320 | | 2 | 0.0951 | 0.555 | 0.555 | 0.501 | Detected | |
| LOD Spike | | 3 | 0.0857 c | 0.500 | 0.500 | 0.501 | Detected | |
| Topas 6015 | 8-7972 | 1 | <0.0858 | <0.501 | | | | |
| Lot No.970320 | | 2 | <0.0858 | <0.501 | | | | |

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

b Concentration corrected by subtracting the mean level detected in the control, when necessary.

c The value was extrapolated below the standard curve.

Table 11

Validation of Norbornene in 10% Ethanol Extracts of Topas® 8007

| Sample Identification | Covance Log Number | Replicate | Concentration Detected (µg/mL) | | Corrected Concentration Detected (µg/in.$^2$)[b] | Concentration Added (µg/in.$^2$) | Percent Recovery | Mean (%) |
|---|---|---|---|---|---|---|---|---|
| | | | | (µg/in.$^2$)[a] | | | | |
| Topas 8007 | 8-7973 | 1 | 0.0699 c | 0.408 | 0.408 | 0.501 | Detected | Detected |
| Lot No. 970205 | | 2 | 0.0829 c | 0.484 | 0.484 | 0.501 | Detected | |
| LOD Spike | | 3 | 0.0679 c | 0.396 | 0.396 | 0.501 | Detected | |
| Topas 8007 | 8-7973 | 1 | <0.0858 | <0.501 | | | | |
| Lot No. 970205 | | 2 | <0.0858 | <0.501 | | | | |

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

b Concentration corrected by subtracting the mean level detected in the control, when necessary.

c The value was extrapolated below the standard curve.

Table 12

Validation of Norbornene in 95% Ethanol Extracts of Topas® 8007

| Sample Identification | Covance Log Number | Replicate | Concentration Detected (µg/mL) | | Corrected Concentration Detected (µg/in.$^2$)[b] | Concentration Added (µg/in.$^2$) | Percent Recovery | Mean (%) |
|---|---|---|---|---|---|---|---|---|
| | | | | (µg/in.$^2$)[a] | | | | |
| Topas 8007 | 8-7973 | 1 | 0.0792 c | 0.462 | 0.462 | 0.501 | Detected | Detected |
| Lot No. 970205 | | 2 | 0.0685 c | 0.400 | 0.400 | 0.501 | Detected | |
| LOD Spike | | 3 | 0.101 | 0.589 | 0.589 | 0.501 | Detected | |
| Topas 8007 | 8-7973 | 1 | <0.0858 | <0.501 | | | | |
| Lot No. 970205 | | 2 | <0.0858 | <0.501 | | | | |

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

b Concentration corrected by subtracting the mean level detected in the control, when necessary.

c The value was extrapolated below the standard curve.

Table 13

Validation of Decalin in 10% Ethanol Extracts of Topas® 6015

| Sample Identification | Covance Log Number | Replicate | Concentration Detected (µg/mL) | | Concentration Detected (µg/in.$^2$)[a] | Corrected Concentration Detected (µg/in.$^2$)[b] | Concentration Added (µg/in.$^2$) | Percent Recovery | Mean (%) |
|---|---|---|---|---|---|---|---|---|---|
| Topas 6015 | 8-7972 | 1 | 0.0626 | c | 0.365 | 0.365 | 0.501 | Detected | Detected |
| Lot No.970320 | | 2 | 0.0368 | c | 0.215 | 0.215 | 0.501 | Detected | |
| LOD Spike | | 3 | 0.108 | | 0.630 | 0.630 | 0.501 | Detected | |
| Topas 6015 | 8-7972 | 1 | <0.0858 | | <0.501 | | | | |
| Lot No.970320 | | 2 | <0.0858 | | <0.501 | | | | |

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

b Concentration corrected by subtracting the mean level detected in the control, when necessary.

c The value was extrapolated below the standard curve.

Table 14

Validation of Decalin in 95% Ethanol Extracts of Topas® 6015

| Sample Identification | Covance Log Number | Replicate | Concentration Detected (µg/mL) | Concentration Detected (µg/in.$^2$)[a] | Corrected Concentration Detected (µg/in.$^2$)[b] | Concentration Added (µg/in.$^2$) | Percent Recovery | Mean (%) |
|---|---|---|---|---|---|---|---|---|
| Topas 6015 | 8-7972 | 1 | 0.0826 | c 0.482 | 0.482 | 0.501 | Detected | Detected |
| Lot No.970320 | | 2 | 0.0887 | 0.517 | 0.517 | 0.501 | Detected | |
| LOD Spike | | 3 | 0.0893 | 0.521 | 0.521 | 0.501 | Detected | |
| Topas 6015 | 8-7972 | 1 | <0.0858 | <0.501 | | | | |
| Lot No.970320 | | 2 | <0.0858 | <0.501 | | | | |

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

b Concentration corrected by subtracting the mean level detected in the control, when necessary.

c The value was extrapolated below the standard curve.

Table 15

Validation of Decalin in 10% Ethanol Extracts of Topas® 8007

| Sample Identification | Covance Log Number | Replicate | Concentration Detected (µg/mL) | | Concentration Detected (µg/in.$^2$)[a] | Corrected Concentration Detected (µg/in.$^2$)[b] | Concentration Added (µg/in.$^2$) | Percent Recovery | Mean (%) |
|---|---|---|---|---|---|---|---|---|---|
| Topas 8007 | 8-7973 | 1 | 0.0731 | c | 0.426 | 0.426 | 0.501 | Detected | Detected |
| Lot No. 970205 | | 2 | 0.0912 | | 0.532 | 0.532 | 0.501 | Detected | |
| LOD Spike | | 3 | 0.0715 | c | 0.417 | 0.417 | 0.501 | Detected | |
| Topas 8007 | 8-7973 | 1 | <0.0858 | | <0.501 | | | | |
| Lot No. 970205 | | 2 | <0.0858 | | <0.501 | | | | |

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

b Concentration corrected by subtracting the mean level detected in the control, when necessary.

c The value was extrapolated below the standard curve.

Table 16

Validation of Decalin in 95% Ethanol Extracts of Topas® 8007

| Sample Identification | Covance Log Number | Replicate | Concentration Detected (µg/mL) | | Concentration Detected (µg/in.$^2$)[a] | Corrected Concentration Detected (µg/in.$^2$)[b] | Concentration Added (µg/in.$^2$) | Percent Recovery | Mean (%) |
|---|---|---|---|---|---|---|---|---|---|
| Topas 8007 | 8-7973 | 1 | 0.0808 | c | 0.471 | 0.471 | 0.501 | Detected | Detected |
| Lot No. 970205 | | 2 | 0.0745 | c | 0.435 | 0.435 | 0.501 | Detected | |
| LOD Spike | | 3 | 0.0716 | c | 0.418 | 0.418 | 0.501 | Detected | |
| Topas 8007 | 8-7973 | 1 | <0.0858 | | <0.501 | | | | |
| Lot No. 970205 | | 2 | <0.0858 | | <0.501 | | | | |

a Concentration (µg/in.$^2$) = Concentration (µg/mL) x (700 mL/120 in.$^2$)

b Concentration corrected by subtracting the mean level detected in the control, when necessary.

c The value was extrapolated below the standard curve.

**SIGNATURES**

M. M. McCort-Tipton

Melanie M. McCort-Tipton
Study Director
Covance Laboratories Inc.

5/21/99
Date

Keith R. Rowley
Associate Director
Covance Laboratories Inc.

5/21/99
Date

# APPENDIX A

## Methods

Analysis of Norbornene and Decalin in 10% Ethanol Extracts

A solid phase micro-extraction (SPME) fiber was used for analysis of norbornene and decalin in the 10% ethanol extracts. The SPME fiber is a fused silica fiber coated with 100 µm polydimethylsiloxane. Three milliliters of extract was placed in a 1-dram vial, containing a Teflon® coated stir bar, with a septum screw cap. The 1-dram vial was placed on a magnetic stir plate. The SPME needle was inserted through the septum into the stirring solution. The fiber remained immersed in the solution for 17 minutes, after which the analytes were thermally desorbed in the gas chromatograph (GC) injection port for 0.40 minutes. The GC parameters are presented below.

GC Parameters

| | |
|---|---|
| Column | DB-1 (30 m x 0.53 mm)<br>3 µm film thickness |
| Detector: | Flame ionization |
| Temperatures: | |
| Column: | 65°C for 5 minutes, then 15°C/minute to 215°C, 215°C for 1 minute |
| Injector: | 250°C |
| Detector: | 300°C |
| Flows: | |
| Carrier: | 8 mL/minute Helium |
| Makeup: | 30 mL/minute Nitrogen |
| Air: | 380 mL/minute |
| Hydrogen: | 37 mL/minute |

Analysis of Norbornene and Decalin in 95% Ethanol Extracts

An aliquot of the 95% ethanol extract was placed in an autosampler vial and analyzed under the following GC parameters.

GC Parameters

| | |
|---|---|
| Column | DB-1 (30 m x 0.53 mm)<br>3 μm film thickness |
| Detector: | Flame ionization |
| Temperatures: | |
| Column: | 50°C for 5 minutes, then 10°C/minute to 250°C, 250°C for 1 minute |
| Injector: | 250°C |
| Detector: | 300°C |
| Flows: | |
| Carrier: | 8 mL/minute Helium |
| Makeup: | 30 mL/minute Nitrogen |
| Air: | 380 mL/minute |
| Hydrogen: | 37 mL/minute |
| Injection volume: | 2 μL |

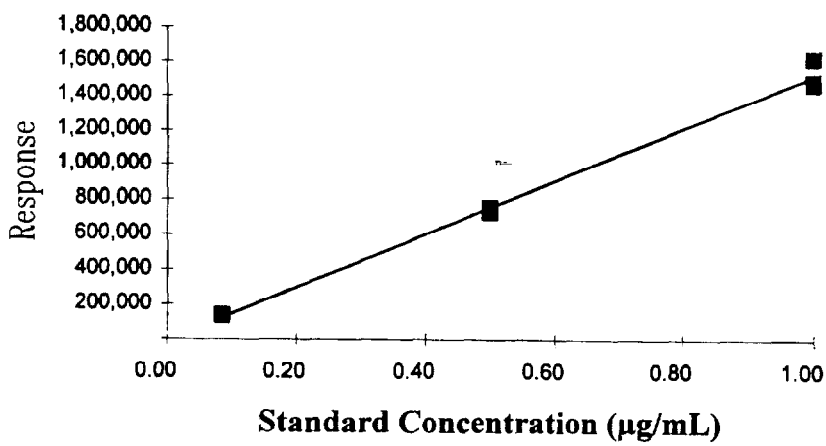
## APPENDIX B

## Example Standard Curve and Chromatography

Example Standard Curve for Norbornene in 10% Ethanol[a]

| Standard Concentration (µg/mL) | Response |
|---|---|
| 0.0858 | 131,805.5 |
| 0.0858 | 136,879.6 |
| 0.500 | 727,636.8 |
| 0.500 | 753,252.2 |
| 1.00 | 1,483,185.4 |
| 1.00 | 1,471,349.2 |
| 1.00 | 1,620,023.4 |

Correlation Coefficient: 0.9969

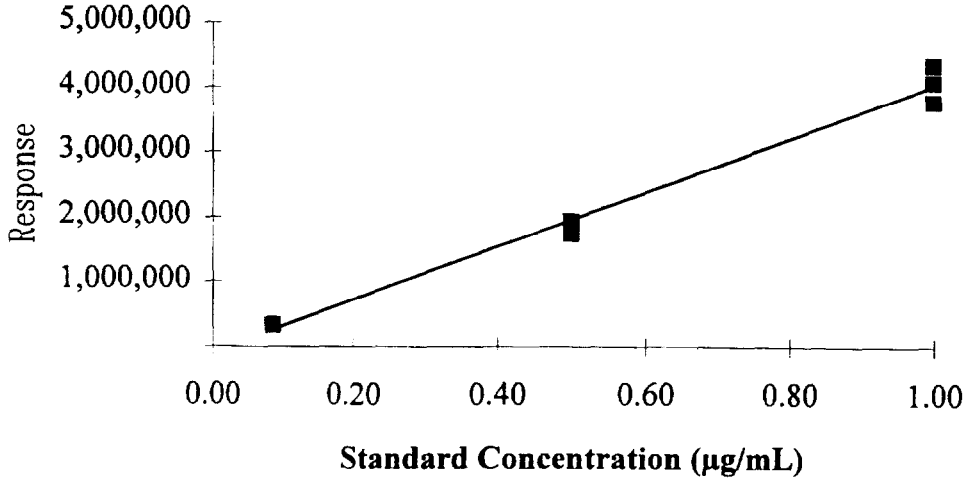



a This is a representative standard curve to demonstrate the linearity of the method.

Example Standard Curve for Decalin in 10% Ethanol[a]

| Standard Concentration (µg/mL) | Response |
|---|---|
| 0.0858 | 319,118.1 |
| 0.0858 | 315,755.6 |
| 0.500 | 1,745,313.8 |
| 0.500 | 1,941,128.0 |
| 1.00 | 4,082,608.6 |
| 1.00 | 3,779,481.5 |
| 1.00 | 4,349,379.3 |

Correlation Coefficient: 0.9937




Please note that the response is the sum of the cis and trans isomers of decalin.

a This is a representative standard curve to demonstrate the linearity of the method.

Figure B1

0.0858 µg/mL Norbornene and Decalin Standard in 10% Ethanol

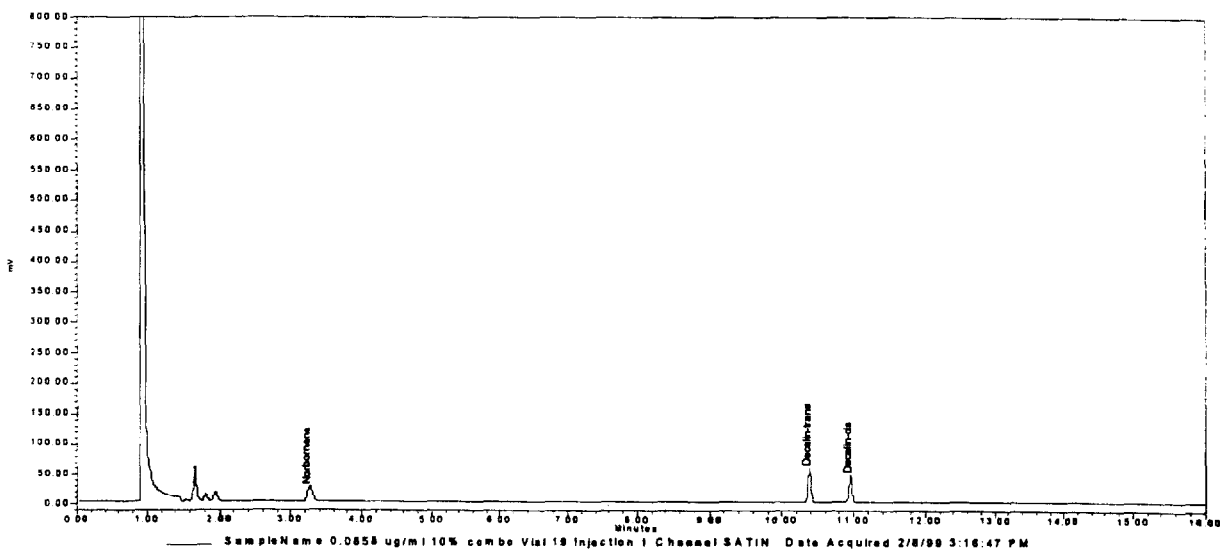



Figure B2

0.500 µg/mL Norbornene and Decalin Standard in 10% Ethanol

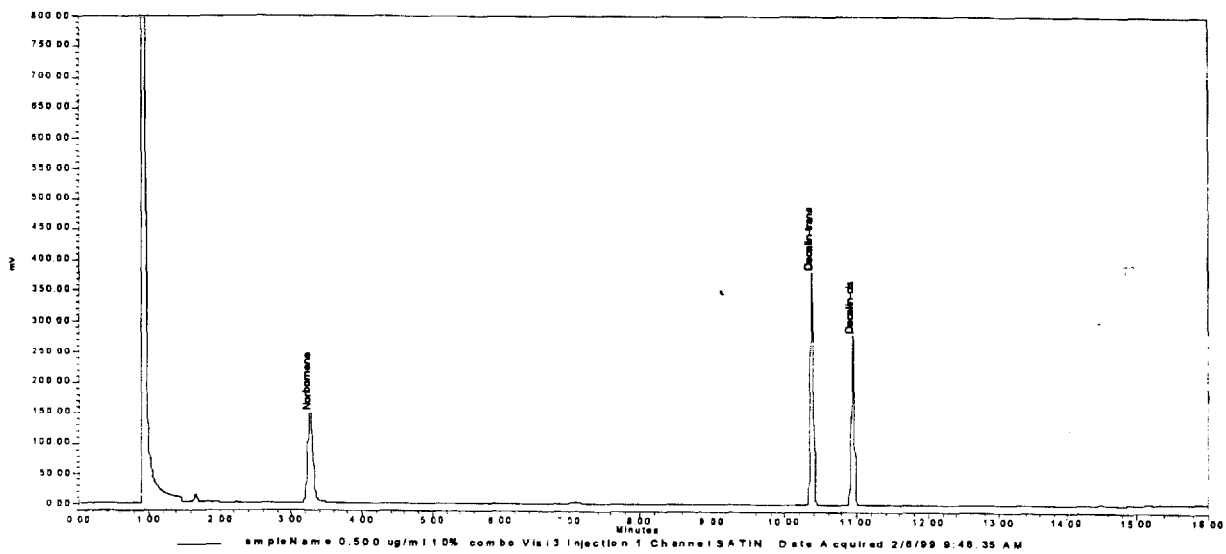


Figure B3

1.00 µg/mL Norbornene and Decalin Standard in 10% Ethanol

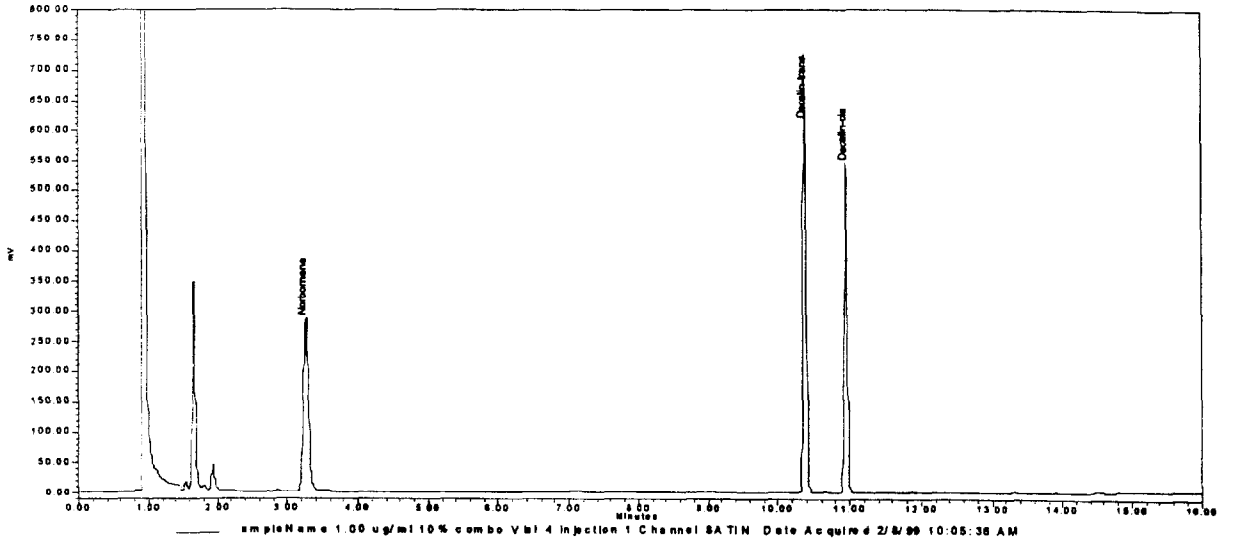



Figure B4

10% Ethanol Analysis, Solvent Blank, 240-Hour

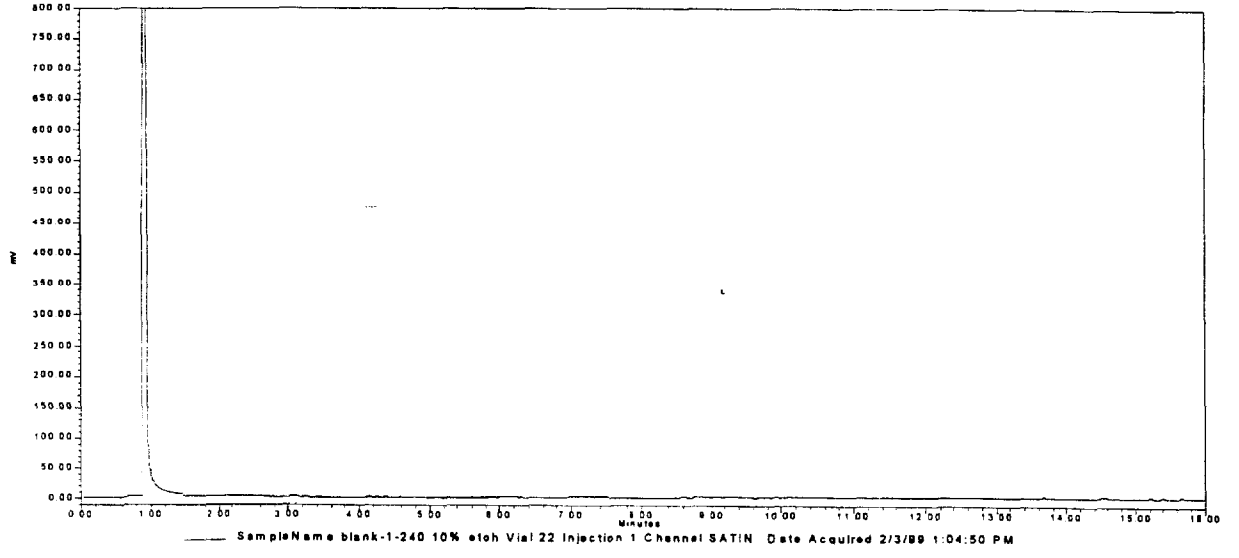


Figure B5

10% Ethanol Analysis, Topas® 6015, 8-7972, 240-Hour Extract

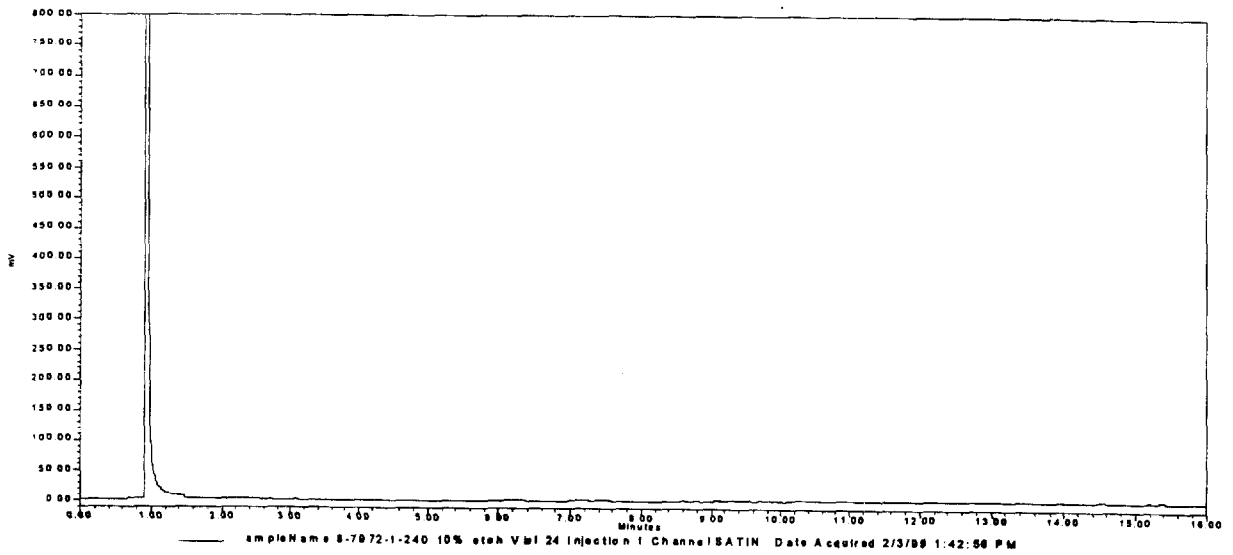



Figure B6

10% Ethanol Validation, Topas® 6015, 8-7972, 240-Hour Composite

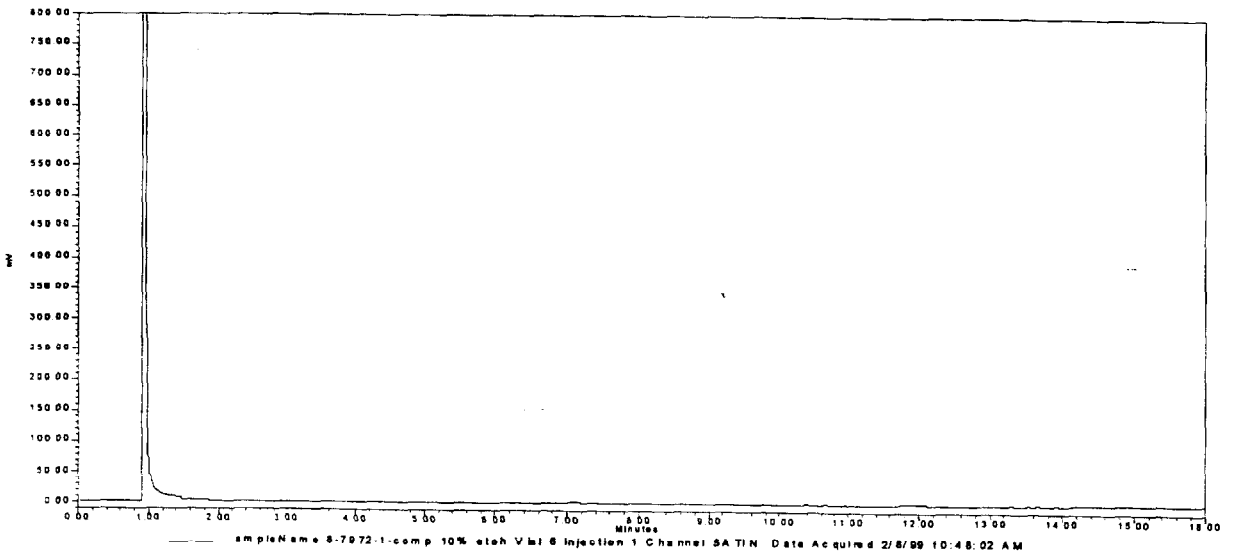


Figure B7

10% Ethanol Validation, Topas® 6015, 8-7972, LOD Spike

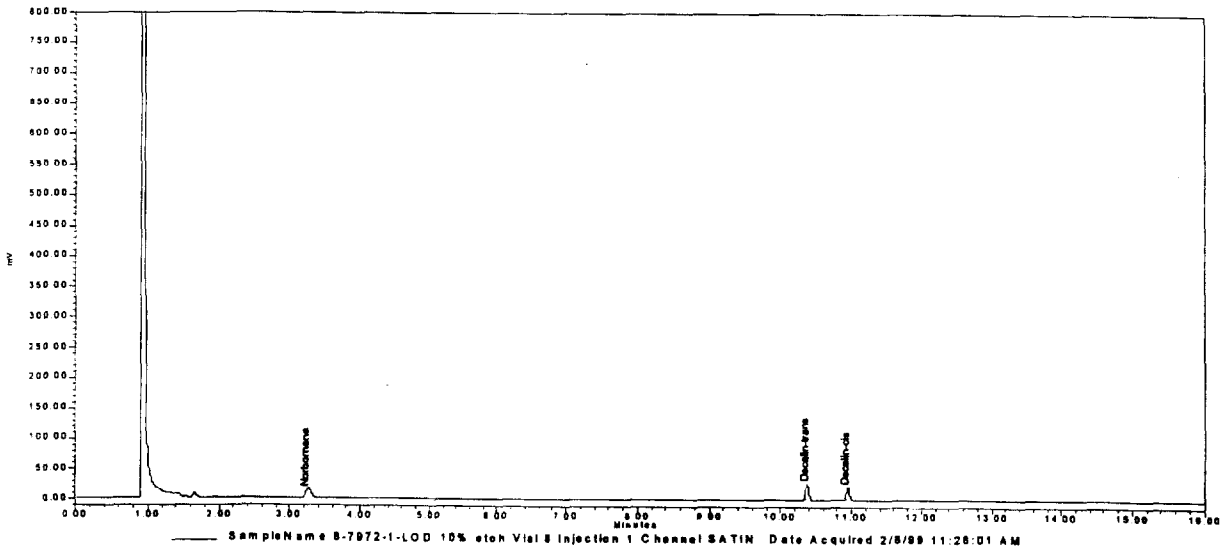



Figure B8

10% Ethanol Analysis, Topas® 8007, 8-7973, 240-Hour Extract

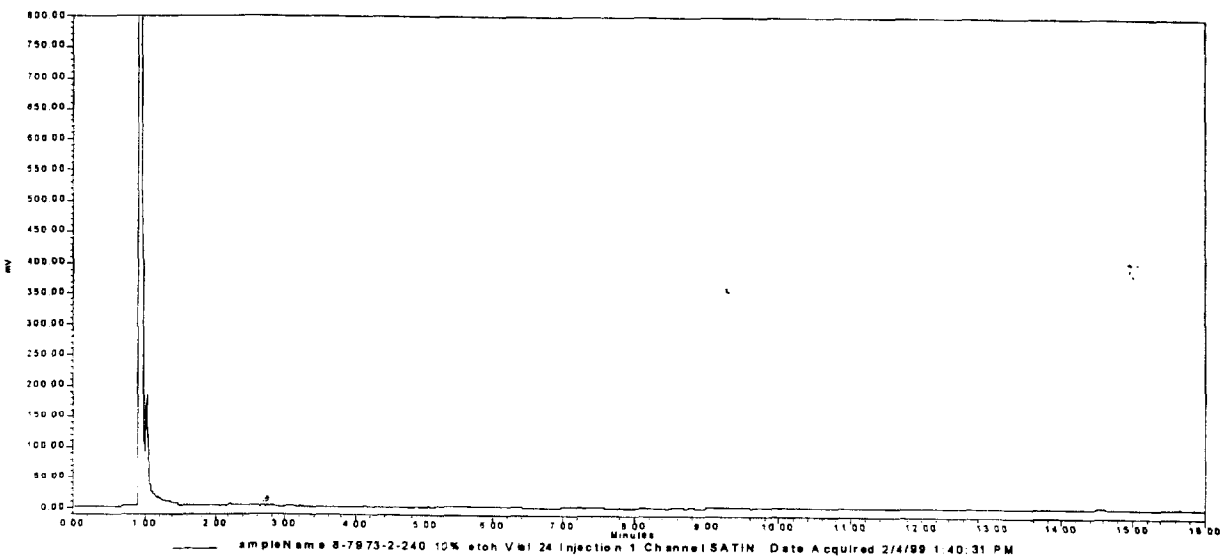


Figure B9

10% Ethanol Validation, Topas® 8007, 8-7973, 240-Hour Composite

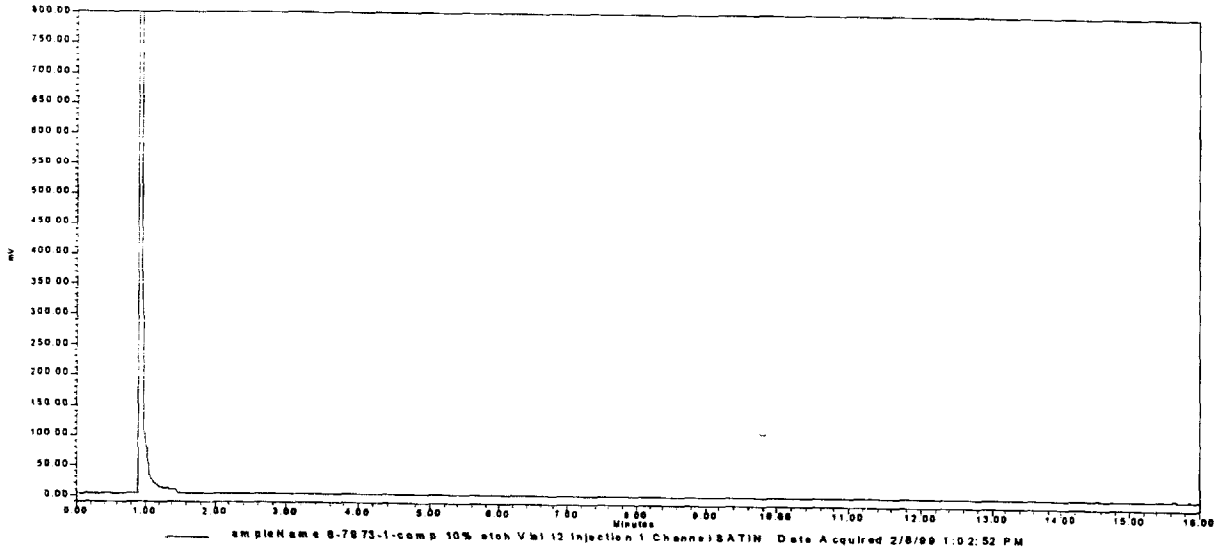
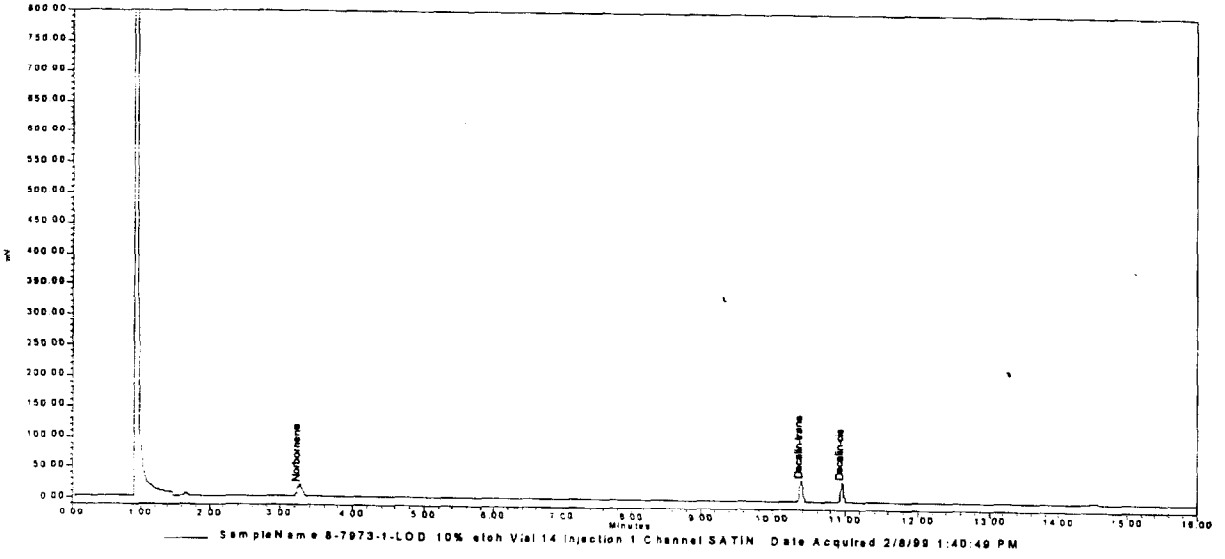


Figure B10

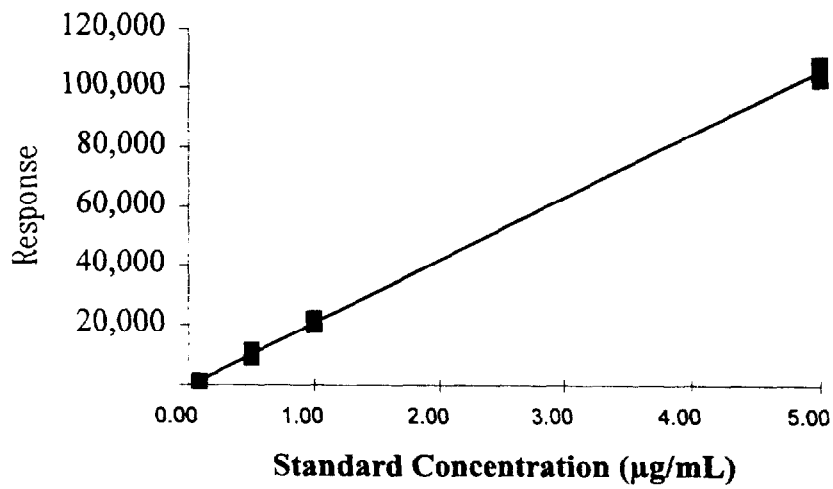
10% Ethanol Validation, Topas® 8007, 8-7973, LOD Spike



Example Standard Curve for Norbornene in 95% Ethanol[a]

| Standard Concentration (µg/mL) | Response |
|---|---|
| 0.0858 | 1,081.7 |
| 0.0858 | 1,143.2 |
| 0.500 | 11,324.3 |
| 0.500 | 8,978.8 |
| 1.00 | 22,175.8 |
| 1.00 | 20,088.2 |
| 5.00 | 108,082.6 |
| 5.00 | 106,264.4 |
| 5.00 | 102,760.7 |

Correlation Coefficient: 0.9995

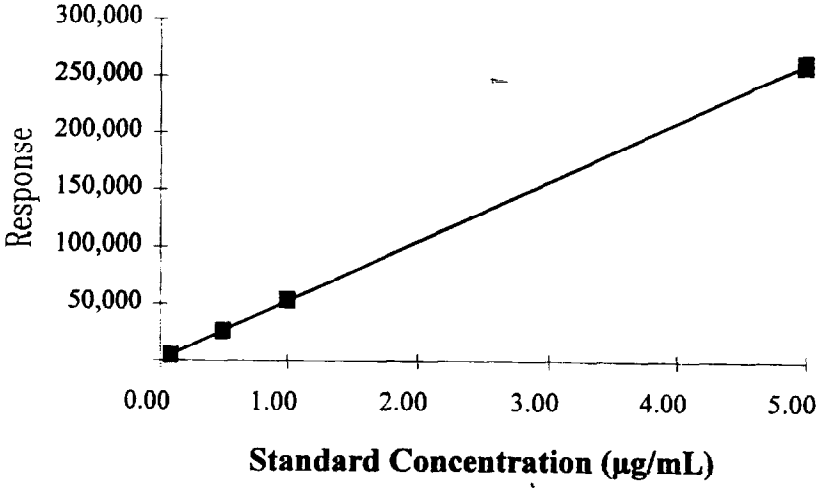



a This is a representative standard curve to demonstrate the linearity of the method.

Example Standard Curve for Decalin in 95% Ethanol[a]

| Standard Concentration (µg/mL) | Response |
|---|---|
| 0.0858 | 4,982.7 |
| 0.0858 | 4,668.2 |
| 0.500 | 26,712.0 |
| 0.500 | 25,816.5 |
| 1.00 | 54,091.3 |
| 1.00 | 52,794.4 |
| 5.00 | 262,774.6 |
| 5.00 | 262,094.4 |
| 5.00 | 258,683.2 |

Correlation Coefficient: 0.9999




Please note that the response is the sum of the cis and trans isomers of decalin.

a This is a representative standard curve to demonstrate the linearity of the method.

Figure B11

0.0858 µg/mL Norbornene and Decalin Standard in 95% Ethanol

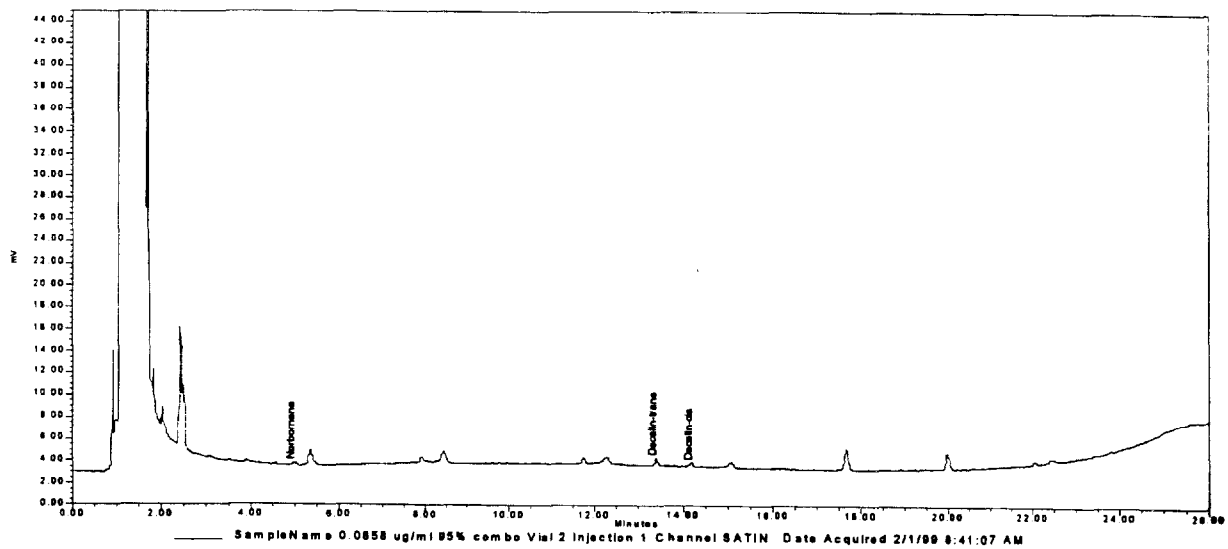



Figure B12

0.500 µg/mL Norbornene and Decalin Standard in 95% Ethanol

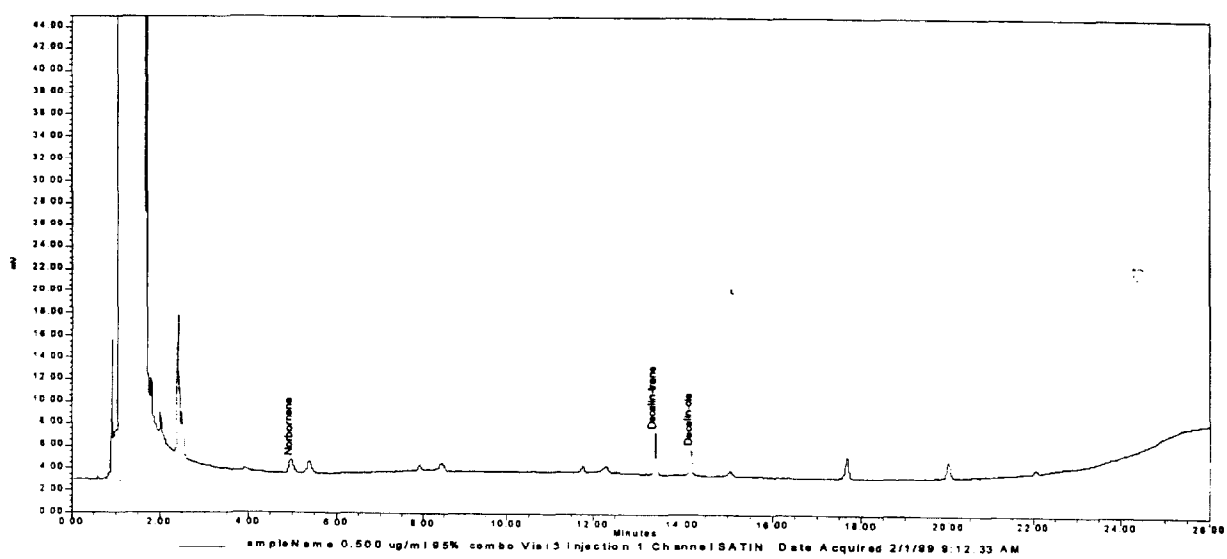


Figure B13

1.00 µg/mL Norbornene and Decalin Standard in 95% Ethanol

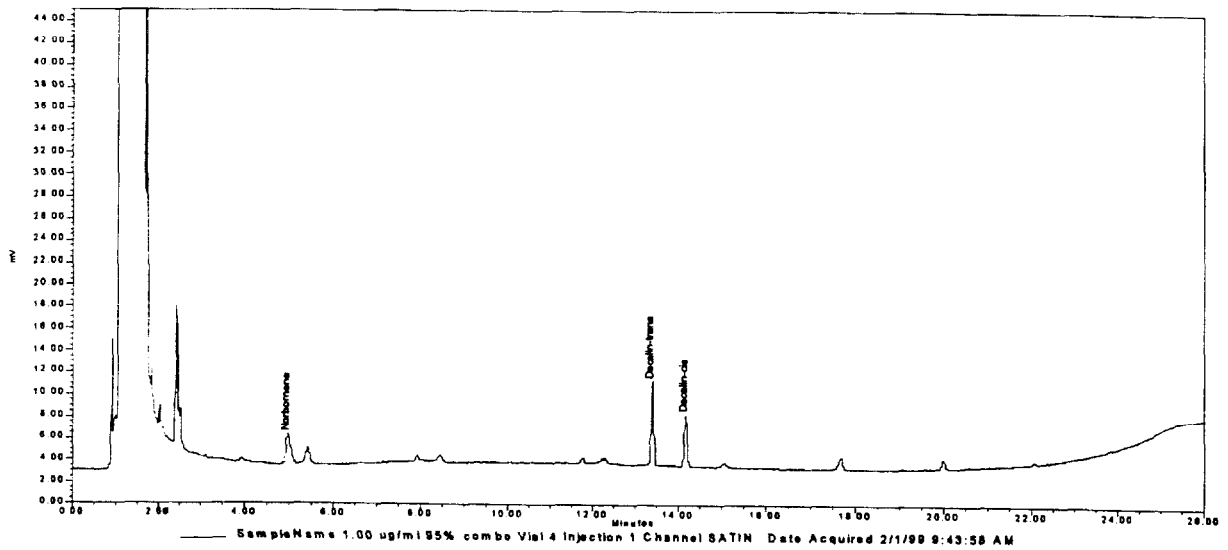



Figure B14

5.00 µg/mL Norbornene and Decalin Standard in 95% Ethanol

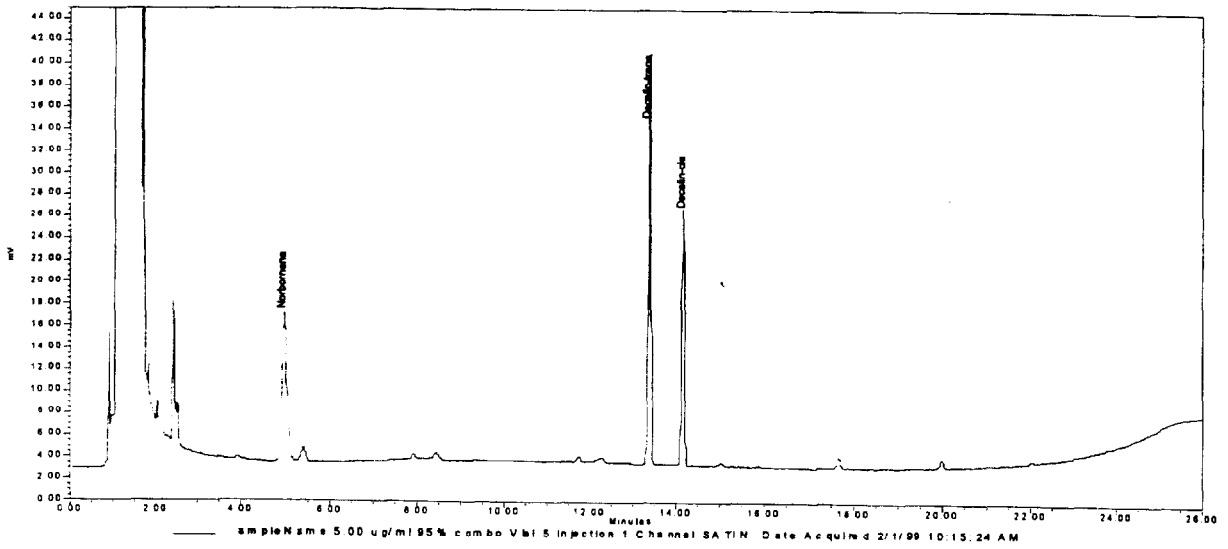


Figure B15

95% Ethanol Analysis, Solvent Blank, 240-Hour Extract

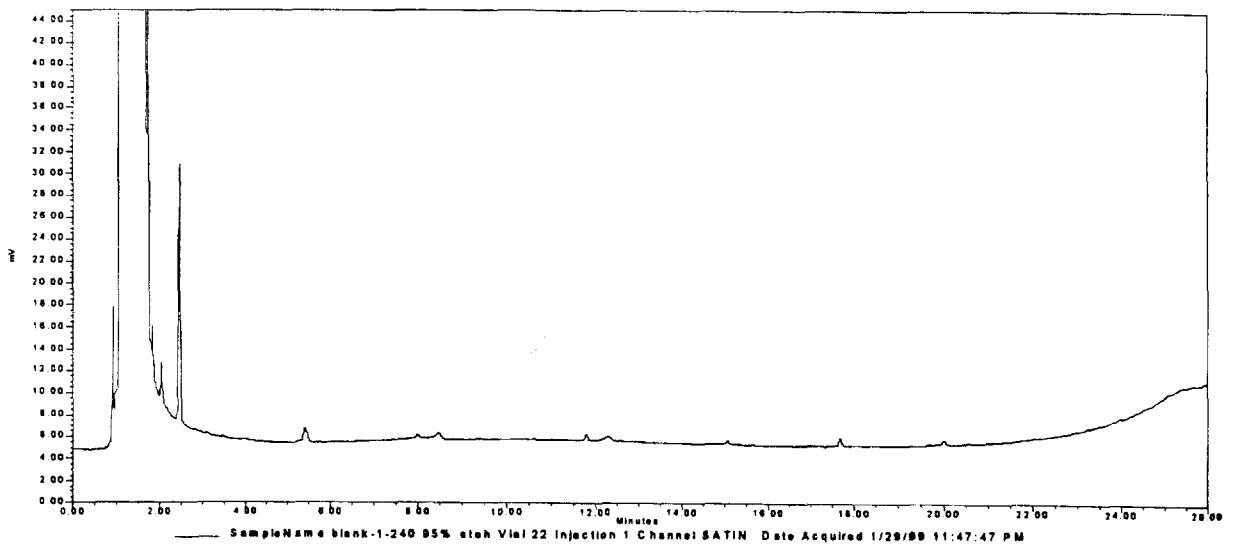



Figure B16

95% Ethanol Analysis, Topas® 6015, 8-7972, 240-Hour Extract

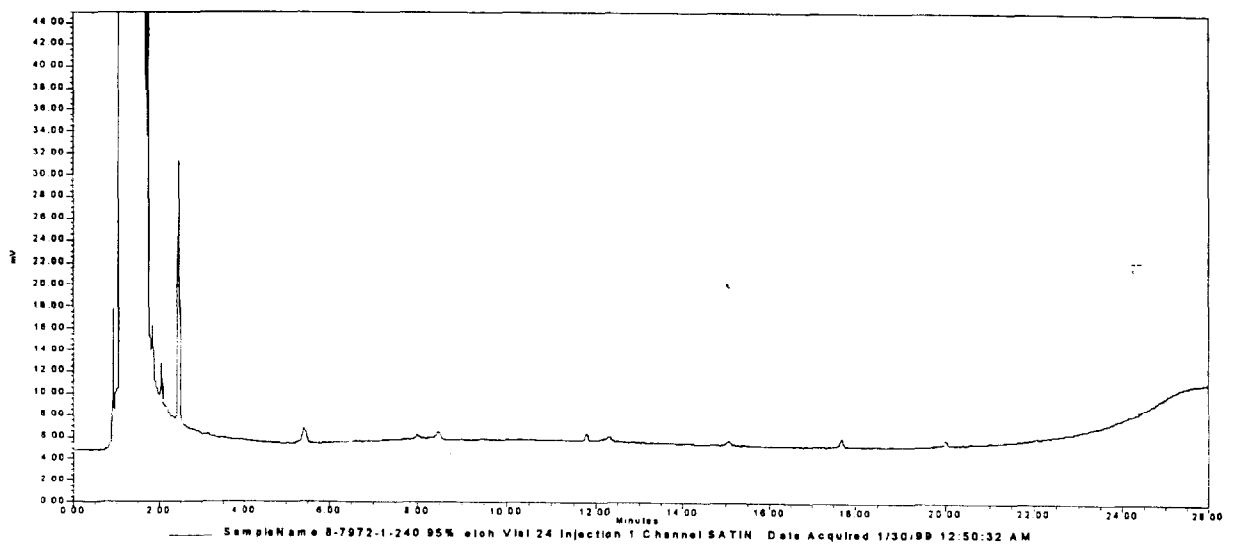


Figure B17

95% Ethanol Validation, Topas® 6015, 8-7972, 240-Hour Composite

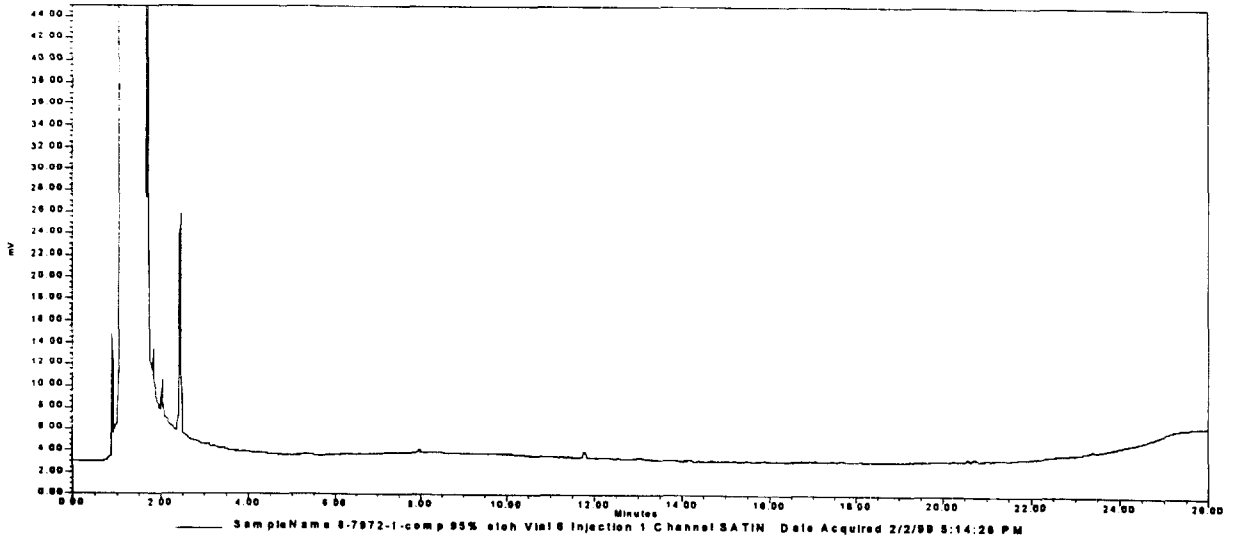



Figure B18

95% Ethanol Validation, Topas® 6015, 8-7972, LOD Spike

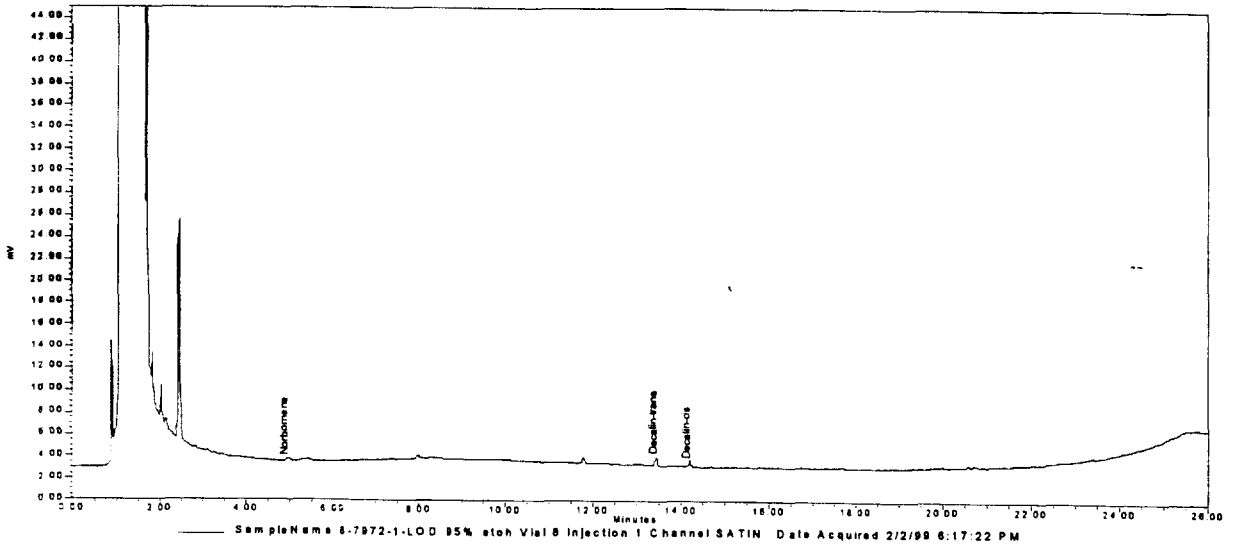


Figure B19

95% Ethanol Analysis, Topas® 8007, 8-7973, 240-Hour Extract

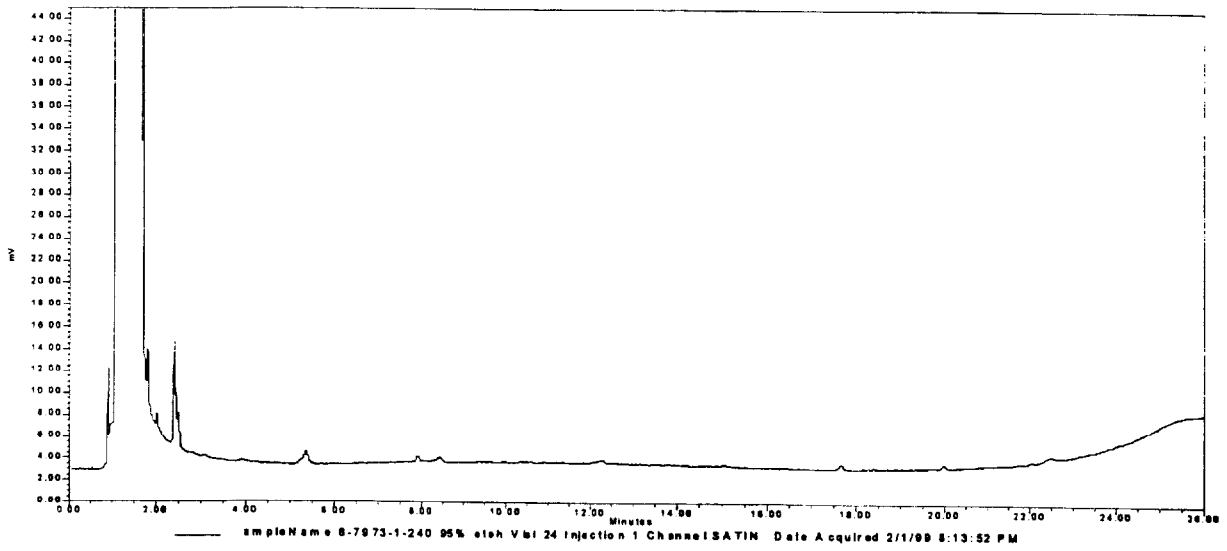



Figure B20

95% Ethanol Validation, Topas® 8007, 8-7973, 240-Hour Composite

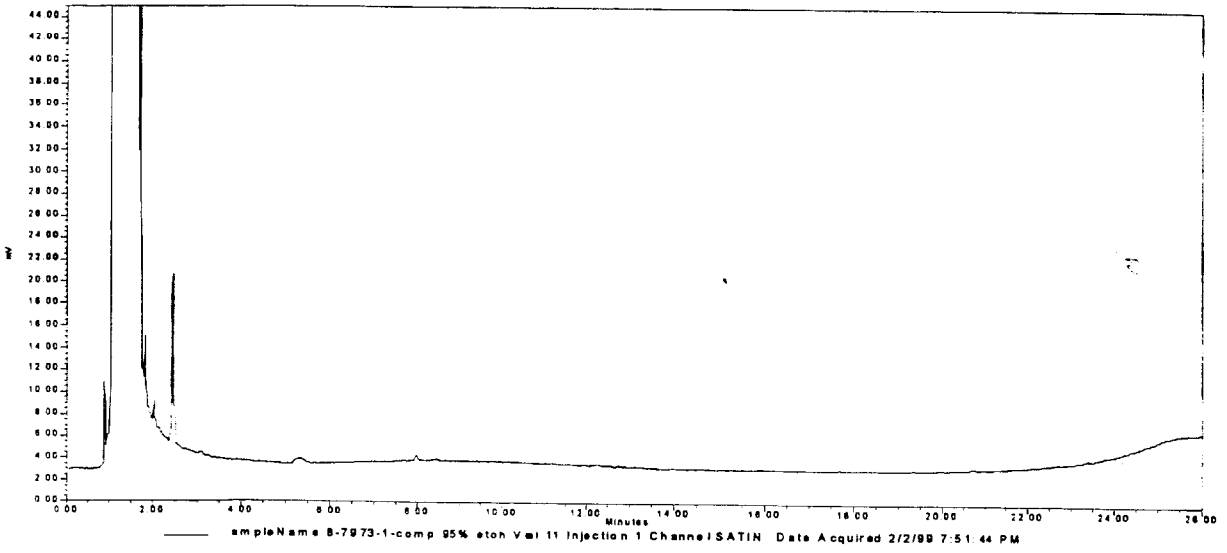


Figure B21

95% Ethanol Validation, Topas® 8007, 8-7973, LOD Spike